

(iii) sealing the periphery of said impermeable cover to tissue surrounding the wound; and

(iv) operably connecting said suction port with a vacuum system for producing said reduced pressure; and

(b) maintaining said reduced pressure until the wound has progressed toward a selected stage of healing.

*4* 80. (Amended Once) An appliance for administering a reduced pressure treatment to a wound comprising:

- a. an impermeable cover adapted to cover and enclose the wound and to maintain reduced pressure at the site of the wound, wherein said cover is sufficiently rigid to support said cover out of contact with the wound;
- b. a seal adapted to seal said cover to tissue surrounding the wound wherein said seal includes a cuff around the periphery of said cover for preventing said cover from digging into the skin during the treatment; and
- c. reduced pressure supply means adapted to connect to a source of suction, said reduced pressure supply means cooperating with said cover to supply said reduced pressure beneath the cover, and said reduced pressure supply means comprising a suction port on said cover.

#### REMARKS

The Office Action Summary states that claims 38-86 were rejected. However, the Office Action contains no specific objection or rejection to claims 39, 40, 43, 49-58, 63-65, 67, 68, 70, 73, 75, 76, 79, 81 and 83-86. Consequently, Applicants are unable to respond relative to these claims. In response to the Action, Applicants have amended claims 38, 43, 60, 72, and 80, and canceled claims 42, 70, 81 and 82.

#### REJECTIONS UNDER 35 U.S.C. 102

Claims 38, 42, 44-48, 59-62, 69, 71, 72, 74, 80, and 82 were rejected under 35 U.S.C. 102 (b) as being anticipated by Harvey.

The device of Harvey is "formed from a single sheet of synthetic transparent plastic... which may be molded under heat and pressure... [to form] a central upstanding elongated dome structure." Harvey, column 2, lines 1-6. In contrast Applicants' invention, as recited in independent claim 38 includes "an impermeable cover adapted to cover and enclose the wound and to maintain reduced pressure at the site of the wound... [and] support means separate from said cover for holding said cover out of contact with the wound..." Also, independent claim 60, amended to incorporate the subject matter of claim 70, recites "an impermeable cover... [and] support means separate from said cover for holding said cover out of contact with the wound..." Harvey does not teach the support means as recited in Applicants' independent claims 38 and 60. Thus, Harvey fails to disclose each and every element of Applicants' invention, and therefore a rejection under 35 U.S.C. 102 cannot stand. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejections to independent claims 38 and 60. Claims 44-48, 59, 61, 62, 69, and 71 which depend from either Independent claim 38 or Independent claim 60, are patentable for at least the same reasons cited above. Accordingly, Applicants respectfully request that the Examiner withdraw the rejections to dependent claims 44-48, 59, 61, 62, 69, and 71.

The dependent claims are patentable for additional reasons as well. For example, additional features exist which distinguish claims 46-48, 61, and 62 over Harvey. Since Harvey does not disclose a support means as claimed by Applicants, Harvey does not disclose that the "support means connects with said sheet..." as recited in Applicants' claim 46; nor does Harvey disclose that the "support means comprises a support member located between said sheet and the wound" as recited in Applicants' claim 47; nor does Harvey disclose that the "support member includes a porous cup..." as recited in Applicants' claim 48. In addition, Harvey fails to disclose a collection device in a vacuum system of the type that "includes means for halting said application of reduced pressure to the wound when said [collected] fluid exceeds a predetermined quantity" as recited in Applicants' claim 62. For these additional reasons, Harvey fails to disclose the subject matter of Applicants' claims 46-48 and 62. Applicants therefore respectfully request that the Examiner withdraw the rejection to claims 46-48 and 62 for these additional reasons as well.

With respect to Applicants' claim 72, Harvey fails to disclose Applicants' claimed steps of "(ii) providing a separate support to support said cover out of contact with the wound" and "(b) maintaining said reduced pressure until the wound has progressed toward a selected stage of healing." In Harvey, there is no disclosure of a support that is separate from the cover. Furthermore, Harvey fails to disclose that pressure should be maintained until the wound has progressed toward a selected stage of healing. Instead, Harvey only teaches that its dressing is connected with a drainage pump for the purpose of draining liquid from a wound. Harvey also fails to disclose "alternating periods of application and non-application of the negative pressure" as recited in Applicants' claim 74. Since Harvey does not disclose each and every element of Applicants' invention as recited in claims 72 and 74, Applicants respectfully request that the Examiner withdraw the rejections to claims 72 and 74.

Applicants have amended independent claim 80 to incorporate subject matter of dependent claim 81. Claim 80 now includes the feature of a seal having "a cuff around the periphery of said cover for preventing said cover from digging into the skin during treatment." This feature is not disclosed in Harvey. Therefore, claim 80 is patentably distinguishable over Harvey and, accordingly Applicants respectfully request that the Examiner withdraw the rejection to claim 80.

#### **REJECTIONS UNDER 35 U.S.C. 103**

The Examiner has rejected claims 41, 66, 77 and 78 under 35 U.S.C. 103 (a) as being unpatentable over Harvey, because "Harvey discloses the claimed device except for the specific ranges of pressure and time..." First, because claims 41, 66, 77 and 78 depend from independent claims 38, 60, or 72, which, as argued above, are now in allowable condition, dependent claims 41, 66, 77 and 78 are also now in allowable condition for at least the same reasons. Independent claims 38, 60, and 70 each recite the feature of employing a support separate from the cover. Harvey lacks any such teaching or disclosure. Accordingly, more than just the "specific ranges of pressure and time" are missing from Harvey. Therefore the rejection under 35 U.S.C. 103 fails to address each and every element of Applicants' invention. Accordingly, the rejection under 35 U.S.C. 103 cannot stand. Second, as recognized by the Examiner, Harvey does not disclose "the

specific ranges of pressure and time." The Examiner, however, applies no prior art reference which teaches or discloses the specific ranges of pressure and time claimed by Applicants. Even more importantly, the Examiner fails to apply any references that teach such subject matter in combination with the remaining subject matter claimed by Applicant. Applicants respectfully submit that the Examiner must cite a reference, or in the alternative, supply an affidavit from the Examiner, in accordance with MPEP 2144.03 and 37 CFR 1.104(d)(2). As an additional matter, dependent claim 77 relates to Applicants' method in which a selected stage of healing is a reduction in bacterial density of at least 50%. There is no disclosure whatsoever in Harvey that addresses this claimed feature of Applicants' invention. For the above reasons, Applicants respectfully request that the Examiner reconsider and withdraw the rejections to claims 41, 66, 77 and 78.

Applicants respectfully request notification of allowance of all pending claims, including claims 39, 40, 43, 49-58, 63-65, 67, 68, 73, 75, 76, 79, and 83-86, to which no specific objections or rejections were made.

The Examiner is invited to telephone the undersigned in the event that a telephone interview will advance prosecution of this application.

Respectfully submitted,



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